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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

Applicant's remarks under 37 CFR 1.116, in reply to the final rejection, have been considered but is not deemed to place the application in condition for allowance for the following reasons.

Claims 1-6, 8-23, and 96-109 are pending. Claims 5-6, 9-18, 20-23, and 96-108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/30/2008. Claims 1-4, 8, 19, and 109 are currently under examination.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 8, 19, and newly submitted claim 109 are directed to an invention not patentably distinct from claims 1-5, 10, 15, 18, and 20-28 of commonly assigned application

11/543,312 and claims 1, 12, and 19 of commonly assigned application 11/770,608. The claims are not considered to be distinct for the reasons set forth below in the double patenting rejections.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned applications 11/543,312 and 11/770,608, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1-4, 8, 19, and newly submitted claim 109 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10, 15, 18, and 20-28 of copending Application No. 11/543,312 for the reasons set forth in the previous office action.

Applicant has not traversed this rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to methods of diagnosing severe sepsis in a human subject comprising determining the concentration of MPIF-1 (and TNF-R1) in a fluid test sample from a human subject and comparing the concentration of said analytes to a reference concentration so that the concentration of the analyte in the test sample is indicative of the presence of severe sepsis.

The claims of copending application 11/543,312 are drawn to methods of diagnosing severe sepsis by assaying CCL23 (which is an alternate name for MPIF-1) and sTNFR1a and

diagnosing the presence of severe sepsis. The claims also include limitations where the sample is blood, serum, or plasma. This method would necessarily include a comparison to a reference concentration to determine whether the level was high enough to warrant the diagnosis. Applicant has added a limitation stating that an elevation of the analyte of about two-fold, relative to the reference concentration is indicative of the presence of severe sepsis. However, the fact that an elevation of two-fold (or four-fold) is indicative of severe sepsis does not add any method steps and is simply a fact that would be true whether it is recognized or not.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 8, 19, and newly submitted claim 109 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, and 19 of copending Application No. 11/770,608 for the reasons set forth in the previous office action.

Applicant has not traversed this rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to methods of diagnosing severe sepsis in a human subject comprising determining the concentration of MPIF-1 (and TNF-R1) in a fluid test sample from a human subject and comparing the concentration of said analytes to a reference concentration so that the concentration of the analyte in the test sample is indicative of the presence of severe sepsis.

The claims of copending application 11/770,608 are drawn to methods of diagnosing severe sepsis by assaying CCL23 (which is an alternate name for MPIF-1) and sTNFR1a and diagnosing the presence of severe sepsis. The claims also include limitations where the sample is blood, serum, or plasma. This method would necessarily include a comparison to a reference concentration to determine whether the level was high enough to warrant the diagnosis. Applicant has added a limitation stating that an elevation of the analyte of about two-fold, relative to the reference concentration is indicative of the presence of severe sepsis. However,

the fact that an elevation of two-fold (or four-fold) is indicative of severe sepsis does not add any method steps and is simply a fact that would be true whether it is recognized or not.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-4, 8, 19, and 109 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant argues:

1. That the examiner has failed to analyze paragraphs 0011, 0012, 0145, and 0196 in the context of the entire application. Applicant argues that it is clear throughout the specification that the invention is directed to the diagnosis of sepsis and/or severe sepsis by measuring the biomarkers identified in the application. Applicant points to paragraphs 0017 and 0018, stating that these disclose methods for "diagnosis of severe sepsis if the concentration of at least one analyte is elevated relative to a reference sample." Applicant refers to paragraphs 0041-0055 to show examples of statistical analysis to identify biomarkers that are significantly different between sepsis samples and reference samples. Applicant also refers to Examples 6 and 7, as well as paragraphs 0145, 0196, and 0204, stating that these show studies where markers, such as MPIF-1 and TNF-R1 are elevated two fold or more in sepsis patients in comparison to control samples.

2. That the examiner's argument that paragraph 0196 contradicts paragraph 0145 is without merit. Applicant argues that throughout the specification it is made clear that some

biomarkers of severe sepsis are elevated while others are depressed and states that the fact that the concentration of some biomarkers decreases during sepsis does not contradict the fact that the concentration of other biomarkers can be used for diagnosis of severe sepsis.

3. That, with respect to claim 109, the recitation "wherein an elevation in concentration of MPIF-1 in the test sample of about four fold relative to the reference concentration is indicative of the presence of severe sepsis in said human" is fully described in the specification. Applicant again refers to paragraph 0196 to show that the specification describes that "MPIF-1 levels are elevated four fold in sepsis patients as compared to sick controls."

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant has previously amended the claims to read on severe sepsis, as opposed to sepsis. The specification specifically differentiates the two terms, defining sepsis on page 1 and severe sepsis on page 3. Thus, these terms are NOT equivalent. References to sepsis in the specification are therefore not references to severe sepsis. Where the specification describes methods of diagnosing sepsis, this is not a description of a method of diagnosing severe sepsis because they are two different conditions. Applicant's arguments that paragraphs 0041-0055 to show examples of statistical analysis to identify biomarkers that are significantly different between sepsis samples and reference samples and that Examples 6 and 7, as well as paragraphs 0145, 0196, and 0204, show studies where markers, such as MPIF-1 and TNF-R1 are elevated two fold or more in sepsis patients in comparison to control samples may be correct, but are not relevant, as these paragraphs and examples only provide support for methods of diagnosing sepsis, and not for diagnosing severe sepsis. Furthermore, applicant has pointed to paragraphs 0017 and 0018, stating that these disclose methods for "diagnosis of severe sepsis if the concentration of at least one analyte is elevated relative to a reference sample." This is factually incorrect. These paragraphs refer to "diagnosis of deterioration or risk of progression to severe sepsis." If one is at "risk of progression to severe sepsis" then one clearly does not actually have sepsis. These paragraphs again highlight the difference between sepsis and severe sepsis. The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. The original disclosure of a large genus did not support a later filed claim to a previously unnamed single species. See In re

Ruschig, 371 F.2d 990, 154 USPQ 118 (CCPA 1967). In Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000), the court noted that with respect to In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention". In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." The specification does not, at any point, refer to two-fold or four-fold elevations in markers as indicators of severe sepsis, and, because there is a difference between sepsis and severe sepsis, reference to these elevations to diagnose sepsis does not provide support for these elevations in diagnosing severe sepsis.

Regarding argument 2, the question is not whether or not some biomarkers increase while others decrease and if this can be used to diagnose sepsis. The question is whether paragraph 0196 provides support for the limitations in the claims requiring a two or four-fold elevation to diagnose severe sepsis. As discussed above, paragraphs 0145 and 0196 do not mention diagnosis of severe sepsis. Therefore, regardless of whether two or four-fold increases are mentioned, there is not support for the claim. The reason the examiner referred to analytes that are decreased, as opposed to increased, during sepsis, is that, with the exception of claim 109 (where the elevated analyte is MPIF-1), the claims encompass a two-fold increase in any analyte, not just MPIF-1 or TNF-R1. Since paragraph 0196 shows a decrease in some analytes during sepsis, this cannot possibly provide support for a two-fold increase in these analytes.

Regarding argument 3, as stated above and in the previous office action, paragraph 0196 makes no mention of severe sepsis. Since sepsis and severe sepsis have been specifically differentiated and are not equivalent, support for a four fold increase of MPIF-1 in sepsis is not support for a four fold increase of MPIF-1 in severe sepsis.

As outlined previously, applicant has amended claims 1 and 19 to state that severe sepsis is indicated or diagnosed if the concentration of the analytes is elevated "about two fold" relative to the reference concentration. In claim 109, the concentration is elevated "about four fold" above the reference concentration. Applicant points to paragraphs 0011, 0012, 0145, and 0196 to provide support for these limitations. However, paragraphs 0011 and 0012 do not make any mention of two fold elevations of any analyte. Paragraph 0145 states that possible markers for

sepsis should show a two fold elevation and paragraph 0196 states that MPIF-1 shows a four fold elevation; however, neither of these paragraphs mention diagnosis of severe sepsis and paragraph 0196 states that some analytes were significantly lower in sepsis, which contradicts paragraph 0145. Therefore, the two fold and four fold limitations are new matter.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
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